07/28/05 08:44 1 :01/07 NO:873

RECEIVED
CENTRAL FAX CENTER

JUL 2 9 2005

### CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Facsimile No.: 703.746.9195

Kathi Hotchkiss

Attorney Docket: RO0937US (#90568)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Christian von Falkenhausen, Walter Muller and Markus Krumme

Serial No. 10/517,087

Group No.

Filed:

December 16, 2004

Examiner:

For:

ACTIVE SUBSTANCE-CONTAINING FILM-LIKE PREPARATIONS HAVING

IMPROVED CHEMICAL STABILITY, AND PROCESSES FOR THEIR

**PREPARATION** 

Assistant Commissioner of Patents
Office of Initial Patent Examination
Customer Service Center
Washington, D.C. 20231

### REQUEST FOR CORRECTED FILING RECEIPT

- 1. Attached is a copy of the official filing receipt received from the Patent and Trademark Office in the above application for which issuance of a corrected filing receipt is respectfully requested.
  - 2. There is an error in that the following data is:
  - (X) incorrectly entered

and/or

- () omitted
  - (X) Applicant's names
  - () Applicant's address
  - (X) Title
  - () Filing Date

- () Serial No.
- () Foreign/PCT Application Reference
- () Other

in that the filing receipt should read as follows: Correct order of applicant's is:

Christian von Falkenhausen, Meckenheim, GERMANY Walter Muller, Andernach, GERMANY Markus Krumme, Neuwied, GERMANY

and the title should read as follows:

ACTIVE SUBSTANCE-CONTAINING FILM-LIKE PREPARATIONS HAVING IMPROVED CHEMICAL STABILITY, AND PROCESSES FOR THEIR PREPARATION

Enclosed is a copy of the first two pages of the Preliminary Amendment to support the amended title, and a copy of the PCT Publication to support the correct order of the applicant's names.

D. Peter Hochberg Reg. No. 24,603

Enclosures:

Copy of Filing Receipt

First two pages of the Preliminary Amendment

PCT Publication Total Pages 7

D. Peter Hochberg Co., L.P.A. The Baker Building 1940 East 6th Street, Sixth Floor Cleveland, Ohio 44114 216.771.3800

### RECEIVED

**CENTRAL FAX CENTER** 

JUL 2 9 2005



### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address CAMMBRICANER FOR PATENTS F.O. Box 1450 Abstratia, Vujinis 23313-1450

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKÉT NO	DRAWINGS	TOT CLMS	IND CLMS	
10/517.087	12/06/2004	1614	1112	RO0937US (#90568)	1	29	2	

D Peter Hochberg Company 6th Floor 1940 East 6th Street Cleveland, OH 44114 Work

CONFIRMATION NO. 1143
FILING RECEIPT

Copy

Date Mailed: 06/22/2005

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Markus Krumme, Neuwied, GERMANY; Walter Muller, Andernach, GERMANY; Christlan von Falkenhausen, Meckenheim, GERMANY; Proper order

Power of Attorney:

D Hochberg-24603

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/EP03/04816 05/08/2003

Foreign Applications

GERMANY 102 24 612.2 06/04/2002

Projected Publication Date: 09/29/2005

Non-Publication Request: No

Early Publication Request: No

Title

514

Film-shaped preparations with improved chemical stability containing active substances and method for the production thereof Thange per Pteliminary amendment Preliminary Class

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process simplifies the filing of patent applications on the same invention in member countries, but does not result in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

### LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

### **GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls.

## (12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum Internationales Büro



## 

(43) Internationales Veröffentlichungsdatum 11. Dezember 2003 (11.12.2003)

PCT

# (10) Internationale Veröffentlichungsnummer WO 03/101421 A1

(51) Internationale Patentklassifikation?: 31/465 A61K 9/00,

Markus [DIVDE]; Feldkircher Strasse 46, 56567 Neuwied (DE).

(21) Internationales Aktenzeichen:

PCT/EP03/04816

(22) Internationales Anmeldedatum:

8. Mai 2003 (08.05.2003)

(25) Einreichungssprache:

Deutsch

(26) Veröffentlichungssprache:

Deutsch

(30) Angaben zar Priorität:

102 24 612.2

4. Juni 2002 (04.06.2002) 1

(71) Anmelder (für alle Bestimmungsstaaten mit Ausnahme von US); LTS LOHMANN THERAPIE-SYSTEME AG 4DIVDR; Lohmannstrsse 2, 56626 Andermeh (DE).

(72) Erfinder; and

(75) Erfinder/Anmelder (nur für US): VON FALKEN-HAUSEN, Christian [DE/DR]; Merler Ring 7, 53340 Meckenheim (DE), MÜLLER, Walter [DE/DR]; Hindenburgwall 12, 56626 Andernach (DE), KRUMME, (74) Anwalt: FLACCUS, Rolf-Dieter; Bussardweg 12, 50389

- Wesseling (DB).
- (81) Bestimmungsstaaten (national): AU, BR, CA, CN, IL, IN, JP, KR, MX, NZ, PH, PL, RU, US, ZA.
- (84) Bestimmungsatuaten (regional): europäisches Patent (AT, BE, BG, CH, CY, CZ, DE, DK, EB, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR).

#### Erkiärung gemäß Regel 4.17;

Erfindererklärung (Regel 4.17 Ziffer iv) nur für US

#### Veröffentlicht:

... mit internationalem Recherchenbericht

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(54) Title: FILM SHAPED PREPARATIONS WITH IMPROVED CHEMICAL STABILITY CONTAINING ACTIVE SUBSTANCES AND METHOD FOR THE PRODUCTION THEREOF

(54) Bezeichnung: WIRKSTOFFIALTIGE FILMFÖRMIGB ZUBERRITUNGEN MIT VERBESSERTER CHEMISCHER STA-BILITÄT, UND VERFAHREN ZU DEREN HERSTELLUNG

(57) Abstract: The invention relates to a film shaped preparation containing active ingredients for application in the oral cavity or for transmucosal application. The invention is characterised in that the preparation has a peroxide number which is at the most 40.

(57) Zusammenfassung: Eine filmförmige wirkstoffhaltige Zubereitung zur Applikation in der Mundhöhle oder zur transmukosa en Applikation, ist dælunch gekennzeichnet, dass die Zubereitung eine Peroxid Zahl aufweist, die höchstens 40 beträgt.

PAGE 5/7 \* RCVD AT 7/29/2005 8:46:34 AM [Eastern Daylight Time] \* SVR:USPTO-EFXRF-5/24 \* DNIS:7469195 \* CSID:216 771 3804 \* DURATION (mm-ss):02-32

# RECEIVED CENTRAL FAX CENTER

JUL 2 9 2005

### EXPRESS MAIL CERTIFICATION UNDER 37 CFR 1.10

"Express Mail" label number EV203146362US
Date of deposit Dec. le. 4864

Thereby certify that the paper(s) identified above, and any document(s) referred to as attached hereto, is being deposited with the United States Postal Service on the date indicated in an envelope as "Express Mail Post Office to Addressee" and is addressed: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia, 22313-1450.

Sean F. Mellino

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Von Falkenhausen, Müller & Krumme

Serial No.

Filing Date

Herewith

Examiner

Group Art Unit:

Title

ACTIVE SUBSTANCE-CONTAINING FILM-LIKE

PREPARATIONS HAVING IMPROVED CHEMICAL

STABILITY, AND PROCESSES FOR THEIR

PREPARATION (as amended herein)

Attorney File:

RO0937US (#90568)

Mail Stop PCT Commissioner for Patents P O Box 1450 Alexandria, Virginia, 22313-1450

### PRELIMINARY AMENDMENT

Dear Sir:

Please amend the above-referenced application as follows:

2

### In the Title:

Please amend the title of the application from "F ILM-SHAPED PREPARATIONS WITH IMPROVED CHEMICAL STABILITY CONTAINING ACTIVE SUBSTANCES AND METHOD FOR THE PRODUCTION THEREOF" to "ACTIVE SUBSTANCE-CONTAINING FILM-LIKE PREPARATIONS HAVING IMPROVED CHEMICAL STABILITY, AND PROCESSES FOR THEIR PREPARATION."